

K091396

Summary of Safety and Effectiveness

AUG 05 2009

Submitter: Denise Duchene
Cardo Medical Corporation
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Date Prepared: May 4, 2009

Device: Cardo Medical Cervical Plate System

Classification: 87KWQ – Appliance, Fixation, Spinal Intervertebral Body, 21CFR 880.3060, Class II

Predicate Device: Vertebreon Cervical Plate Systems – K040003, K043181, K051815, K062110 and K081567. Cardo Medical Cervical Plate System K073530

Device Description: The Cardo Medical Cervical Plate System consists of titanium cervical plates and both self-tapping and self-drilling screw components. The surgeon uses the components to make a construct that is placed anteriorly for spinal fixation. The construct is used for temporary fixation which allows for fusion of the cervical spine. The modified system includes the addition of a fixed angle cervical screw as an option for the surgeon.

Intended Use: The Cardo Medical Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disk disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); trauma (including fracture); tumor; deformity (defined as kyphosis, lordosis or scoliosis); pseudoarthrosis; and/or failed previous fusions. The Cardo Medical Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7.

Comparison to Predicates:

The Cardo Medical Cervical Plate System consists of plates and screws manufactured from the same titanium alloy as the Vertebreon, Inc. Cervical Plate Systems. Therefore, the devices are equivalent to the Vertebreon, Inc. Cervical Plate System.

Cardo Medical has determined that any differences in the proposed device will not impact the safety or effectiveness of the cervical plate system for its intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance document entitled "Spinal System 510(k)s" dated May 3, 2004, and that the proposed device is equivalent to the predicate device.

Synopsis of Test Methods and Results:

Tests were performed on the cervical plate system. The testing was performed in accordance with ASTM F1717, Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model. The proposed device was equivalent to the predicate device for all testing performed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Cardo Medical Corporation
% Ms. Denise Duchene
1033 US Highway 46, Suite A204
Clifton, New Jersey 07103

AUG 05 2009

Re: K091396

Trade/Device Name: Cardo Medical Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 8, 2009
Received: May 10, 2009

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

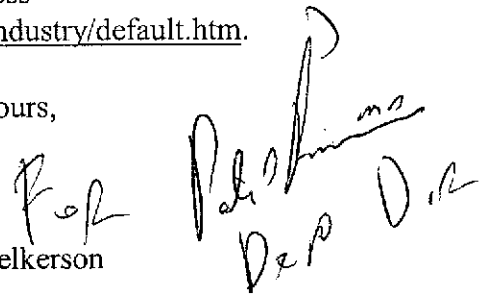
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title. The signature is stylized and cursive.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K091396

Device Name: Cardo Medical Cervical Plate System

Indications for Use:

The Cardo Medical Cervical Plate System components are intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with:

- Degenerative disk disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Trauma (including fractures)
- Tumor
- Deformity (defined as kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions.

The Cardo Medical Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7.

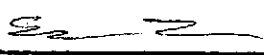
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 (EXT/MXM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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